ECOLAB

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Writer's Direct Dial Number:

July 10, 2000

Documents Management Branch
(HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NUMBER 00N-1262
MAY 5, 2000 *FEDERAL REGISTER* NOTICE
IMPROVING PREMARKET REVIEW AND APPROVAL OF FOOD AND COLOR ADDITIVES IN THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION; REQUEST FOR COMMENTS

Dear Sir or Madam:

Ecolab Inc. (Ecolab) is a manufacturer primarily engaged in the formulation and packaging of institutional and industrial chemical specialty products. Among these products are antimicrobial food additives. Because of the significant impact of the premarket review process has on these products, Ecolab has an interest in the issues posed in this notice.

Ecolab commends FDA for its model efforts in streamlining the premarket approval process for food additive petitions and the premarket notification (PMN) process for food-contact substances in the interest of achieving the goals of the National Food Safety Initiative. On January 31, 2000 FDA announced a memorandum of understanding (MOU) between FDA and the Food Safety Inspection Service of the U.S. Department of Agriculture (FSIS). The purpose of the MOU is to streamline the review and approval of food additives and sources of radiation subject to regulation by FDA and intended for use in the production of meat and meat food products. These streamlining efforts are vital to the rapid commercialization of beneficial antimicrobial additives which will assist food processing establishments in implementation of preventative measures in reducing pathogens to meet the requirements of the Hazard Analysis Critical Control Point (HAACP) regulations.

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FDA has requested comments regarding food and color additive review's in the following areas:

1. What specific changes can be made to the current review process to make it more efficient, transparent, timely, responsive, while preserving the high standards of data review and of safety?

   The Agency should continue to provide and update useful information about the Petition and Premarket Notification review process on the CFSAN website. For example, the document *Questions About the Petition Process* provides information on contacts, preparation of scientific documentation, essential elements of a good petition, and characteristics of the food additive approval process. Providing this level of detail gives the petitioner an excellent reference to ensure a petition or notification is complete and eligible for filing. In addition the detail provided will decrease the number of review cycles between the Consumer Safety Officer (CSO), agency reviewers and the petitioner.

   Ecolab recommends that the above document incorporate the provisions of the recent FDA *Food Additive Expedited Review Guidance* to give further transparency to the food additive petition process. Continuous improvement of these resources, will assist the Agency and industry in building administrative records that document the safety and effectiveness of additives.

2. Should the Center consider broadening the criteria for eligibility for expedited petition review? If so, petitions for what types of uses should be added.

   Ecolab agrees with the Agency's policy to expedite the review of food additive petitions which demonstrate an effectiveness against pathogenic organisms. Although these petitions are expedited, they still have to meet the same approval standards that are applied to other food additive petitions. The Agency should consider expediting petitions for antimicrobial additives that reduce the rate of non-pathogen spoilage organisms which impact sanitary conditions in food processing and retail establishments.

3. How should the increased appropriation to CFSAN that is targeted for the safety review of food and color additives be allocated?

   Ecolab fully supports prefiling consultations as a means to expediting food additive petitions and PMN's. These consultations provide the opportunity for industry to meet with Agency personnel to review new technologies (need and benefit), review data requirements, receive Agency input on proposed protocols prior to data generation, review of preliminary data, discuss safety and

environmental assessment issues, and jurisdiction issues with sister agencies such as EPA and USDA. Mutual agreement resulting from prefiling consultations will increase the efficiency of data generation, filing, review, final approval and reduce cycles between the Agency reviewers, the Consumer Safety Officer and the petitioner.

Enhancing electronic data management will increase the speed of the review/approval process due to simultaneous access by Agency reviewers.

Due to the requirements of HAACP for food processing establishments, the quantity of petitions and notifications will continue to increase. Therefore, more personnel resources may be needed for safety review.

4. What specific program enhancements should be given the highest priority?

Ecolab recommends continuing the expedited review program for food additive petitions, use of prefiling consultations, and electronic data management. FDA should lead partnership efforts with sister agencies to streamline the clearance of antimicrobial food additives which require a food additive regulation under the Federal, Food, Drug and Cosmetic Act (FFDCA) and an pesticide registration under the Federal, Insecticide, Fungicide, Rodenticide Act (FIFRA)

Thank you for your attention to our comments.

Sincerely

John G. Wood
Director, Product Registration & Compliance

James A. Westerhaus
Vice President, Regulatory Services

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